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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,229	02/09/2004	Ronald Mathison	024916-013	4016

21839 7590 11/29/2005

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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/773,229	<b>Applicant(s)</b> MATHISON ET AL.	
	<b>Examiner</b> Anish Gupta	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 9-6-05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21,23-32 and 34-50 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-50 is/are allowed.
- 6) ☒ Claim(s) 21,23-32 and 34-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### DETAILED ACTION

1. The amendment, filed 9-6-05, is acknowledged. Claims 22 and 33 were cancelled and claims 42-50 were added. Claims 21, 23-32, 34-50 are pending in this application.

### *Claim Rejections - 35 USC § 112*

#### *First Paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21, 23-32, 34-41 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of inflammation with the peptide FEG and those specific tri-peptides claimed in US 6586403, does not reasonably provide enablement for any peptide corresponding to the formula R1-X1-X2-R2 for the same purpose or prevent inflammatory reactions or prevent infiltration of neutrophils into an inflammatory site. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims.

Applicants argue that the reference relied upon in the rejection, Ngo et al. and Rudinger discuss sequences of lengths beyond those claimed in the instant application. The argument raised do not apply to peptide containing 3 to 8 amino acids. Furthermore, the specification provides tables where activity was assessed for a series of analogs so as to provide guidance to those skilled in the art. Further, the "Examiner has adopted an overly rigid interpretation of the wording 'prevention,' interpreting it to mean absolute and permanent prevention. It is submitted that the

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proper standard for interpreting 'prevention' is one of skill in the art would expect the term to be interpreted, i.e., "a reasonable degree of prevention for a time sufficient to confer a benefit on a subject."

Applicant's response has been considered but has not been found persuasive.

First it is unclear where Applicants have derived their definition for prevention. Secondly, the definition relied upon does not define the term. "A reasonable degree of prevention for a time sufficient to confer benefit on a subject," does not define the degree of benefit that prevention achieves. Using any dictionary, prevention is defined as "to keep from happening or existing" (see Merriam-Webster Online Dictionary, <http://www.m-w.com/dictionary/preventing>) or "to stop (something) from happening or (someone) from doing something" (see Cambridge Dictionary, [http://dictionary.cambridge.org/define.asp?key=prevent\\*1+0&dict=A](http://dictionary.cambridge.org/define.asp?key=prevent*1+0&dict=A)). As stated in the previous office action, the specification does not provide guidance as "to keep from happening or existing" inflammatory reactions in a mammal or infiltration of neutrophils into a inflammatory site.

Note that the Application will be in condition for allowance if Applicants delete the "prevention" limitation from the claims.

The rejection is maintained.

### ***Double Patenting***

The rejection of Claims 21-41, rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,586,403 is hereby withdrawn.

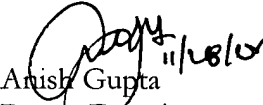
3. Claims 42-50 are allowed.

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4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

  
Anish Gupta  
Patent Examiner